# **IDFNZ FAQ**

Infection with SARS-CoV-2 coronavirus causes COVID-19, which can affect lungs, airways, and other organs. A number of vaccines to prevent COVID-19 have been developed. In New Zealand, the Pfizer-BioNTech COVID-19 mRNA vaccine Comirnaty is the only one currently available, although others have been approved by Medsafe and are likely to arrive in the near future. Everyone aged 12 and over is now eligible to be vaccinated.

About 95% of people who have received both doses of the Pfizer vaccine are protected against getting seriously ill with COVID-19. Although some still get infected, their disease is milder and their infection risk to others is less than in unvaccinated people.

Being vaccinated protects not just you but your community. It is especially important for the family, friends, and close contacts of people with immunodeficiencies to be vaccinated (if over eligibility age). This helps shield vulnerable individuals.

We have addressed some common questions raised by people with immunodeficiencies below. Please note that this is a rapidly evolving area. This information is current as of 7/9/21. If you have concerns about the vaccine that are not covered here, your specialist is the best person to address these.

#### Am I more at risk of getting COVID-19?

So far we don't think so, according to international experience in PID patients.

## If I get it am I more likely to get really sick?

Possibly. Some patients with immunodeficiencies will, but certainly not all, and it may be in those that do it is other risk factors such as lung disease, infection, cancer, obesity, increasing age, or being post-stem cell transplant, that cause this. A review of 480 PID patients with COVID-19 found that about a third of them were asymptomatic or had mild disease. Immunosuppression (e.g after stem cell or organ transplants) is associated with more severe disease.

International research is underway to study patients with severe COVID-19 to see if they have a previously undiagnosed underlying immunodeficiency. This has identified that patients with problems with type I interferon signalling (not previously known to have PID) have very severe disease. Genetic deficiencies of this are extremely rare.

#### What about Delta?

Delta is a more infectious variant. We don't have any data for PID patients and Delta specifically.

#### Can I have the COVID vaccine?

Yes. The COVID-19 vaccine currently in use in NZ is an mRNA vaccine. It contains mRNA for the spike protein; this is a short lived messenger molecule that primes the body to recognise and respond to SARS-CoV-2. It is not a live vaccine and cannot cause the disease. It does not enter the cell nucleus and does not alter your own DNA.

#### When should I get it?

The main thing is to not have your immunoglobulin therapy and the vaccine on the same day; this is so that if you are one of the rare people to have an allergic reaction we can be sure of the cause.

If you are on immunosuppressant medication then check with your specialist as in some cases the timing may need to be adjusted.

The second dose should be given at least three weeks after the first dose.

## Will it work?

To see if a vaccine works we look at clinical data such as the number of people vaccinated who then get COVID-19, as well as how sick they get and how many are admitted/sent to ICU/ventilated. About 95% of people who have received both doses of the Pfizer vaccine are protected against getting seriously ill with COVID-19.

We can also check in the laboratory for SARS-CoV-2 specific antibodies and specific T cells. Antibodies are made by B cells and bind to the virus, preventing it from getting into host cells. T cells kill infected cells, produce proteins that help get rid of the virus, and communicate with B cells to help them respond. Other parts of the immune system are also involved but are harder to measure. We don't yet know how well the laboratory tests relate to clinical protection.

With regard to immunodeficiencies, patients with mild antibody deficiencies (e.g. IgA deficiency, specific antibody deficiency) should have good responses to the vaccine. Patients with disorders of the innate immune system (e.g. CGD or complement deficiencies) should also have good responses.

Patients with more severe antibody deficiencies (XLA, CVID, specific antibody deficiency) may not make antibodies to the vaccine, depending on their deficiency. They should make T cell responses. Some patients with CVID do have T cell impairment as well and may not make good responses.

Patients with combined B and T cell deficiencies (SCID) are unlikely to make good responses to the vaccine. In these patients it is important that their families and close contacts are vaccinated.

Preliminary results from a study in 81 adults with various primary immunodeficiencies found that 85% of them made an antibody response to two doses of the vaccine. Larger studies are underway in PID patients to measure their laboratory values pre and post vaccine, which will provide useful information for us.

We do have some data from immunocompromised patients - those with chronic renal failure, on high dose immunosuppressants, after stem cell or solid organ transplant - that found vaccine effectiveness was 70-80%. This did not include PID patients.

#### Is it safe?

Yes. Most people have mild or no reaction to the vaccine. The most common side effects are pain at the injection site, fatigue, aches, and nausea.

Inflammation of the heart (myocarditis/pericarditis) occurs in small numbers of people receiving mRNA vaccines, less than 40 per million. Most respond well to treatment and settle rapidly. The risk of myocarditis or pericarditis with COVID-19 infection itself is about 6x higher than the risk with the vaccine.

Very small numbers of people - about 5 in a million - have a severe allergic reaction to the vaccine.

# Can I have a test to see if the vaccine worked?

No. Antibody (serology) tests are available in New Zealand, but are mainly used for diagnosing people who've had COVID-19 without knowing it. We don't know what antibody level is protective and so doing a test won't tell you if the vaccine worked. If you have an antibody deficiency then the antibody tests are unlikely to be helpful anyway.

We don't yet have any NZ tests for COVID-19 specific T cells and, as with antibody levels, we don't know what level is protective.

Testing may become available in the future.

# Should I go back to work when we're out of level 4? Do I need to take extra precautions?

At level 3 you need to wear a mask in public and in settings with contact with the public (e.g. visiting healthcare facilities, food venues, on public transport) and gatherings are limited in size. This level implies low or no known cases in the community. We feel that these precautions should also be adequate for immunodeficient patients. In some work settings (e.g. childcare, healthcare, MIQ) it may be higher risk and/or harder to avoid contact; if this is a concern you should discuss this with your specialist.

As the level drops and contact increases, it is likely that extra precautions such as masking and limited crowd numbers will continue given the increased infectivity of the Delta variant. Vaccination rates will also have increased.

## When will my immunoglobulin therapy contain antibodies to COVID?

Significant levels should be present about 6-12 months after widespread vaccine take-up (over 50% fully vaccinated). However, we do not yet know what level is protective.

#### Should I get a booster vaccine shot?

The data about using additional doses is small and the clinical benefits have not been demonstrated. Some countries are using them in high risk immunocompromised patients such as those who've received stem cell or solid organ transplants. This is because small studies have shown that up to half of these patients who did not make an antibody response to the first two doses did make a response to a third dose. However, they did not look at whether those patients who did not make antibody responses actually became infected. None of these studies have included PID patients.

The US have recently authorised a third dose for patients with moderate to severe immunocompromise, including those with primary immunodeficiency. The study mentioned above will hopefully provide more information about the antibody and T cell responses seen to the COVID-19 vaccine in patients with PID

Currently only two doses can be given in New Zealand. It is likely that further doses will be authorised in future but when this will be given, to whom, and which vaccines will be used is not yet decided. Immunocompromised people are likely to be considered a risk group.

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PID/Transplant, Immune compromised and other vulnerable patients have priority access to vaccinations. To book your COVID-19 vaccination go to <u>https://bookmyvaccine.covid19.health.nz</u>.

# Further information on COVID-19 vaccination can be found at:

Unite Against COVID-19 https://covid19.govt.nz/covid-19-vaccines/

The Immunisation Advisory Centre (IMAC) COVID-19 Education <u>https://covid.immune.org.nz/</u> or call 0800 IMMUNE (0800 466 863) for COVID-19 clinical advice and vaccinator assistance from 8am-8pm, seven days

The Ministry of Health site <u>https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-</u>novel-coronavirus/covid-19-vaccines

The ASCIA document 'Allergy, Immunodeficiency, Autoimmunity and COVID-19 Vaccination – Frequently Asked Questions (FAQ) at <u>https://www.allergy.org.au/patients/ascia-covid-19-vaccination-faq</u>